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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,666

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Dan Rottenberg

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EXAMINER

SU, SUSAN SHAN

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

01/05/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/597,666	ROTTENBERG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SUSAN SU	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9,11-13 and 15-19 is/are rejected.
- 7) ☒ Claim(s) 8, 10, 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

Claims 1, 3-6, & 8-19 are pending and examined on the merits.

### ***Priority***

Applicant's claim to benefit of prior-filed Application No. 60/541,267 filed February 3, 2004 is acknowledged and entered into the record.

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1 & 11 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 17-19 are rejected under 35 U.S.C. 102(b) being anticipated by et al. (US 6,527,698, "Kung").

With regard to Claim 17, Kung teaches an in-vivo pressure control method, the method comprising:

implanting (Abstract) a differential pressure regulation device in a body, said pressure regulation device including a shunt placed between two or more chambers of a heart in said body,

Art Unit: 3761

deploying a flow regulating mechanism (it is part of the device that's implanted),  
controlling a setting of said flow regulating mechanism according to changes in pressure differences between said chambers (Col. 4 lines 21-26), and maintaining a flow between said chambers through all pressure differences between said chambers (blood is still allowed to flow between the chambers through the blood vessels).

With regard to Claim 18, Kung also teaches remotely controlling the flow regulating mechanism positioning.

With regard to Claim 19, Kung also teaches reducing a pressure difference between a first chamber and a second chamber (Col. 2 lines 62-67).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 3-6, 9, 11-13, & 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kung.

With regard to Claims 1, 5, 11, & 13, Kung teaches a differential pressure regulating device, the device comprising:

a shunt (30) being positioned between two chambers (atria, see Fig. 1) of a heart in a body, to enable fluids to flow between said chambers, and an adjustable flow regulating mechanism (35), being configured to selectively cover an opening of said shunt, to regulate and keep the flow of fluid through said shunt in relation to a pressure difference between said body chambers (Col. 6 lines 36-39);

a control mechanism (34) to be coupled to said adjustable flow regulating mechanism, to remotely activate said adjustable flow regulating mechanism.

Kung does not expressly teach that the cover is always kept ajar or that it allows a continuous flow of fluid through the shunt. However, Kung teaches that the opening and closing of the cover and the extent (step size) to which the cover opens and closes (Col. 8 lines 1-11) based on a constant measurement of the pressure of the left atrium of the heart. Since the heart is constantly pumping, it is obvious that the cover for the shunt is constantly opened to various degrees to accommodate the increases and decreases in the left atrial pressure and to allow the fluid to flow back and forth between the two chambers during different parts of each cardiac cycle (Col. 6 line 64 to Col. 7 line 14). It would have been obvious to one of ordinary skill in the art at the time of the

Art Unit: 3761

invention to modify Kung by always keeping the cover ajar to maintain an accurate pressure relationship between the two chambers.

With regard to Claims 3 & 15, Kung also teaches that the flow regulating mechanism is to be continually adjustable in accordance with at least one pressure threshold (Col. 7 lines 25-27).

With regard to Claim 4, Kung also teaches that the flow regulating mechanism is to be continually adjustable in accordance with changes in pressure difference between the chambers (Col. 2 line 63 to Col. 3 line 8).

With regard to Claims 6 & 12, Kung also teaches that the control mechanism includes one or more mechanisms selected from the group consisting of: wires, lines, springs, pings, cables, magnets, hooks, latches, electric mechanisms (Col. 6 line 50), pressure transducers, telemetry mechanisms, wireless mechanisms, pneumatic mechanisms, and motors (52).

With regard to Claim 9, Kung also teaches that the flow regulating mechanism is to close the opening of the shunt.

With regard to Claim 16, Kung also teaches that the flow regulating mechanism is rigid (see Fig. 4 and Col. 6 lines 39-42 where screws and shafts are known to be rigid) and its position is directly controlled by said control mechanism (Col. 8 lines 1-5), thereby substantially determining the precise size of the opening of the shunt.

***Allowable Subject Matter***

7. Claims 8, 10, and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

Art Unit: 3761

limitations of the base claim and any intervening claims. No prior art is found to teach or suggest (in combination with Kung) that the differential pressure regulating device is positioned in the interatrial septum of the heart (Claims 8 & 14) or that the flow regulating mechanism is selected from the group as claimed in Claim 10.

### ***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

Art Unit: 3761

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761